UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,381	08/22/2005	Nobuya Kaneko	04208.0210	3951

22852 7590 10/29/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
GAMI, TEJAL	

ART UNIT	PAPER NUMBER
2121	

MAIL DATE	DELIVERY MODE
10/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,381	KANEKO ET AL.	
	Examiner	Art Unit	
	TEJAL J. GAMI	2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to an AMENDMENT entered June 10, 2008 for the patent application 10/517381.

Status of Claims

2. Claims 6 and 9-13 were rejected in the last Office Action dated December 11, 2007.

As a response to the December 11, 2007 office action, Applicant has Amended claims 6, 9, 10, and 13.

Claims 6 and 9-13 are now pending in this office action.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 6 and 9-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter: mathematical abstract and/or algorithm.

Independent Claims 6, 9, and 13 teach a medicine prototype support system. The claims have no associated physical transformation and therefore the claims are considered to recite only the § 101 judicial exceptions of mathematical abstraction and/or algorithm. There is no claim of any agency or means of performing a real-world

state change. While the claims final result may be useful and concrete, it is not tangible. The tangible requirement requires that the claim must recite more than a § 101 exception and set forth a practical application of any § 101 judicial exception to produce a real-world result. Claims 6, 9, and 13 fail to set forth a practical application of a § 101 judicial exception producing a real-world result and is thus considered non-statutory under 35 U.S.C. 101.

Independent Claim 10 teaches a method of requesting. Claim 10 produces the same final result as Claims 6, 9, and 13. Claim 10 is thus non-statutory under 35 U.S.C. 101 for the same reason as Claims 6, 9, and 13.

Since claims 11 and 12 depend from claim 10, without curing the defects, claims 11 and 12 are considered non-statutory under 35 U.S.C. 101.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 6 and 9-13 is rejected under 35 U.S.C. 102(e) as being anticipated by Norris et al. (WO 01/65441).

As to independent claim 6, Norris discloses a medicine prototype support system for an ingredient manufacturer developing medical product (e.g., pharmaceutical) at a request of a product manufacturer (see Page 5, First Paragraph) comprising:

a database comprising main ingredient information (e.g., stored in the system database) (see Page 5, Last Paragraph);

communication means (e.g., server) for receiving main ingredient information from the data base (e.g., formulation data) (see Page 11, Last Line of Second Paragraph);

information conversion means for selecting a second main ingredient having properties similar (e.g., comparison 809) to a confidential (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) first main ingredient (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), communication means (e.g., server) for transmitting second main ingredient information (e.g., formulation) and composition ingredient information (e.g., components) to a composition manufacturer system (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System); and

composition ingredient determination means for selecting a composition ingredient based on the properties of the first and second main ingredients (see Page 8, Section 1. Formulation Know-How), wherein the medicine prototype support system is configured to receive a request for prototype manufacture including the confidential first

main ingredient information from the product manufacturer (e.g., affiliate) (see Page 11, First Paragraph), to select the second main ingredient using the information conversion means (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient using the composition ingredient determination means (see Page 8, Section 1. Formulation Know-How), and to transmit a second request for prototype manufacture including the second main ingredient information (e.g., formulation) and the composition ingredient information (e.g., components) to the composition manufacturer system (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System), the first confidential main ingredient information is confidential information of the product manufacturer (e.g., granted access to formulations the affiliates decide to make available to them) (see Page 5, Last Line of Second Paragraph), and the medicine prototype support system does not reveal the identity of the confidential first main ingredient to the composition manufacturer system (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph).

As to independent claim 9, Norris discloses a medicine prototype support system for an ingredient manufacturer developing medical product (e.g., pharmaceutical) at a request of a product manufacturer (see Page 5, First Paragraph) comprising:

a database including main ingredient information (e.g., stored in the system database) (see Page 5, Last Paragraph);

information conversion software that selects a second main ingredient having properties similar (e.g., comparison 809) to a confidential (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) first main ingredient (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), composition ingredient determination software that selects a composition ingredient based on the properties of the first and second main ingredients (see Page 8, Section 1. Formulation Know-How); and

a server (e.g., server) for transmitting second main ingredient information (e.g., formulation) and composition ingredient information (e.g., components) to a composition manufacturer system (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System; and Page 10, Last Paragraph), wherein the medicine prototype support system is configured to receive a request for prototype manufacture including the confidential first main ingredient information from the product manufacturer (e.g., affiliate) (see Page 11, First Paragraph), to select the second main ingredient using the information conversion means (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient using the composition ingredient determination means (see Page 8, Section 1. Formulation Know-How), and to transmit a second request for prototype manufacture including the second main ingredient information (e.g., formulation) and the composition ingredient information (e.g., components) to the composition manufacturer system (e.g., customer for assembly)

(see Page 13, Third Paragraph of Section 6. Formulation System), the first main ingredient information is confidential information of the product manufacturer (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph), the second main ingredient information is non-confidential (e.g., granted access to formulations the affiliates decide to make available to them) (see Page 5, Last Line of Second Paragraph), and the medicine prototype support system does not reveal the identity of the confidential first main ingredient to the composition manufacturer system (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph).

As to independent claim 10, Norris discloses a method of requesting prototype manufacture from a composition manufacturer (see Page 5, First Paragraph) comprising the steps of:

receiving a first request for prototype manufacture (e.g., manufacture of pharmaceuticals) (see Page 5, First Paragraph) from a product manufacturer (e.g., affiliate) (see Page 11, First Paragraph), the request including main ingredient information that is confidential (e.g., authorization; granted access) information of the product manufacturer (see Page 5, Last two Paragraphs);

storing (e.g., stored in the system database) the confidential first main ingredient information (see Page 5, Last two Paragraphs);

selecting a second main ingredient having properties similar (e.g., comparison 809) to the confidential main ingredient (see Figure 8 for "a flow diagram of a general

process for a user to sort through a formulation database to select a set of matching formulations);

determining a composition ingredient based on the confidential main ingredient information and second main ingredient information (see Page 8, Section 1. Formulation Know-How);

transmitting a second request for prototype manufacture to the composition manufacturer (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System), the request for prototype manufacture including the identities of the selected second main ingredient (e.g., formulation) and the selected composition ingredient (e.g., components) (see Page 13, Third Paragraph of Section 6. Formulation System); and

maintaining the confidentiality of the first main ingredient information by not transmitting it to the composition manufacturer (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph).

As to independent claim 13, Norris discloses a medicine prototype support system for an ingredient manufacturer developing medical product (e.g., pharmaceutical) at a request of a product manufacturer (see Page 5, First Paragraph) comprising:

a database comprising main ingredient information (e.g., stored in the system database) (see Page 5, Last Paragraph);

information conversion means for selecting a second main ingredient by comparing (e.g., comparison 809) (see Figure 8) properties of a confidential main

ingredient stored in the database (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) with properties of a plurality of potential second main ingredients stored in the database (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations);

composition ingredient determination means for selecting a composition ingredient based on the properties of the first and second main ingredients (see Page 8, Section 1. Formulation Know-How); and

communication means (e.g., server) for receiving confidential first main ingredient information from a product manufacturer (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) and for transmitting selected second main ingredient information (e.g., formulation) and composition (e.g., components) ingredient information to a composition manufacturer system (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System), wherein the medicine prototype support system is configured to receive a request for prototype manufacture including the confidential first main ingredient information from the product manufacturer (e.g., affiliate) (see Page 11, First Paragraph), to select the second main ingredient using the information conversion means (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient using the composition ingredient determination means (see Page 8, Section 1. Formulation Know-How), and to transmit a second request for

prototype manufacture including the second main ingredient information (e.g., formulation) and the composition ingredient information (e.g., components) to the composition manufacturer system (e.g., customer for assembly) (see Page 13, Third Paragraph of Section 6. Formulation System), the first confidential main ingredient information being confidential information of the product manufacturer (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph), the medicine prototype support system does not reveal the identity of the confidential first main ingredient to the composition manufacturer system (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) and the information conversion means (e.g., server) selects the second main ingredient such that it is impossible to estimate the development of the confidential first main ingredient from the second main ingredient (e.g., privately maintained formulation data) (see Page 11, Second Paragraph).

As to dependent claim 11, Norris teaches the method of claim 10, further comprising transmitting a second request for prototype manufacture to a second composition manufacturer (see Page 7, First Paragraph of Detailed Description of the Invention).

As to dependent claim 12, Norris teaches the method of claim 10, wherein the confidential main ingredient information received from the product manufacturer (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) includes the identity of the main ingredient (e.g., formulations are developed by

combining ingredients) (see Page 8, First Sentence of Section 1. Formulation Know-How).

Response to Arguments

7. Applicant's amendment and arguments filed June 10, 2008 have been fully considered. The amendment does not overcome the original art rejection and the arguments are not persuasive. The following are the Examiner's observations in regard thereto.

Applicant Argues:

The "formulations" discussed in Norris do not correspond to the claimed requests for prototype manufacture. Instead of requests for manufacture, the formulations are "product specifications ... [that] impart the understanding to build at least a prototype product." Id. at 7, 11-13.

Examiner Responds:

Examiner is not persuaded. See prior art page 5, lines 4-6 where Norris discloses for example, manufacture of pharmaceuticals. Under such considerations, the prior art anticipates requests for manufacture.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tejal J. Gami whose telephone number is (571) 270-1035. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert DeCady can be reached on (571) 272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Albert DeCady/
Supervisory Patent Examiner
Tech Center 2100

/TJG/

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/517,381	KANEKO ET AL.	
	Examiner	Art Unit	
	TEJAL J. GAMI	2121	